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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,581	07/31/2003	Anne-Marie Rodriguez	0857/70669	5002

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John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

HAMA, JOANNE

ART UNIT	PAPER NUMBER
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1632

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,581	Applicant(s) RODRIGUEZ ET AL.	
	Examiner JOANNE HAMA	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12,25-28 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,25-28 and 48-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/2/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on April 2, 2008 has been entered.

Claims 8, 13-24, 29-47 are cancelled. Claims 1, 11, 25 are amended.

Claims 1-7, 9-12, 25-28, 48-54 are under consideration. It is noted that claims 11 and 12 are now under consideration, see "Claim Objections" below.

Information Disclosure Statement

Applicant has filed an Information Disclosure Statement (IDS) on April 2, 2008. The IDS has been considered. It is noted that the reference, Pittenger et al., 1999 has been lined through and indicated as being a duplicate ("dup") of the reference cited by the Examiner in the 892 filed May 22, 2006.

Withdrawn Rejections/Objection***Claim Objections***

Applicant's arguments, see pages 8-9 of Applicant's response, filed April 2, 2008, with respect to the objection of claims 11, 12 have been fully considered and are persuasive. Applicant indicates that claim 11 has been amended such

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that claim 11 only depends from claim 9. The objection of claims 11, 12 has been withdrawn.

35 USC § 112, 2nd parag.

Applicant's arguments, see page 9 of Applicant's response, filed April 2, 2008, with respect to the rejection of claims 25-28, 48 have been fully considered and are persuasive. Applicant indicates that claim 25 has been amended to recite process steps. The rejection of claims 25-28, 48 has been withdrawn.

35 USC § 102

Applicant's arguments, see pages 9-14 of Applicant's response, filed April 2, 2008, with respect to the rejection of claims 1-7, 9-12, 48-54 as being anticipated by Katz et al., WO 00/53795 have been fully considered and are persuasive. Applicant indicates that the method steps of the instant invention are different from that taught by Katz et al. WO 00/53795. Applicant indicates that the instant invention indicates that the source of the stem cells are from a child under 10 years of age and procedures such as liposuction are not performed on young children. As such, the cells taught by Katz et al. are not the same as the instant invention (Applicant's response, pages 13-14). The rejection of claims 1-7, 9-12, 48-54 has been withdrawn.

Applicant's arguments, see pages 15-16, filed April 2, 2008, with respect to the rejection of claims 1-7, 9-12, 48-54 as being anticipated by Zuk et al., 2001 have been fully considered and are persuasive. Applicant indicates that Zuk et al. do not teach that adipose tissue is obtained from a child under the age of 10

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(Applicant's response, page 16). The rejection of claims 1-7, 9-12, 48-54 has been withdrawn.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-12, 26-28, 48, 51, 52 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to indicate that the claimed cell has "beta-galactosidase activity of less than 0.05% at 60 population doublings". It is unclear what the 0.05% is relative to. Claims 2-7, 9-12, 26-28, 48, 51, 52 depend on claim 1 and are included in the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 9-12, 25-28, 48-50, 53, 54 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al., PCT Publication No. WO 00/53795, publication date, September 14, 2000, previously cited, in view of Akanbi et al., 1994, J. Anim. Sci., 72: 2828-2835, Hedrick et al., US Patent Application US 2003/0082152, published May 1, 2003, Haynesworth et al., US Patent 5,733,542, patented March 31, 1998.

Katz et al. teach human lipo-derived stem cells (Katz et al., Example 1). Katz et al. teach that these stem cells can differentiate into adipocytes, osteocytes, myocytes, or chondrocytes (see table on page 18) and that the telomerase activity was similar to that exhibited by previously reported human stem cells (Katz et al., page 18, 1st parag.). Katz et al. also teach how to isolate the stem cells from adipose tissue. Adipose tissue is obtained from liposuction patients, rinsed with PBS, digested with collagenase, and spun twice in a centrifuge. Following the second spin, the cells were plated (Katz et al. Example 1).

While Katz et al. teach that the adipose tissue is obtained from liposuction (and implies the tissue is from adults), Katz et al. do not teach obtaining the tissue from children.

Akanbi et al. teach that adipose precursor cells from young animals replicate faster than cells from older animals and/or contain more clones capable of full differentiation into adipocytes (Akanbi et al., page 2828, 2nd col., 1st parag.).

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It would have been obvious to one of ordinary skill in the art to obtain stem cells from adipose tissue of children using the teachings of Katz et al. and Akanbi et al. An artisan would have taken the method of obtaining stem cells from adipose tissue and carried out the procedure using adipose tissue from children since Akanbi et al. teach that cells obtained from young animals replicate faster and differentiate better than cells obtained from older animals.

It is noted that neither Katz et al. nor Akanbi et al. teach that stem cells obtained from adipose tissue of children have particular characteristics, such as those recited in claim 1. However, because the method of obtaining the stem cells from adipose tissue (Katz et al.) is the same as the claimed invention, the cells obtained from children would have these characteristics. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

With regard to the claims being drawn to cells obtained by selecting "CA" cells that have an adhesion rate of less than 12 hours (claim 25), it is routine in

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the art to plate cells overnight, allow them to adhere to the plate, and rinse them the next day in order to remove debris and residual non-adherent red blood cells (Hedrick et al., page 66, parag. 202). As such, Hedrick et al. teach that it is routine in the art that stem cells can be obtained following overnight plating of cells. With regard to claim 25 being drawn to "enriching the CA population" and "inducing proliferation of CA", Hedrick et al. teach that these plated cells can remain stem cells if they are maintained at sub-confluent levels (Hedrick et al., page 66, parag. 202). Hedrick et al.'s teaching is readable on the claims because Hedrick et al.'s population is enriched by the PBS washing and by keeping the cells confluent to maintain their multipotency.

With regard to the claims being drawn to "CS" cells, wherein the "CS" population comprises a plurality of cells (claims 49 and 50), the claims have been interpreted to mean that the claimed cells are a mixture of cells which comprise CS cells (i.e., "plurality" has been interpreted to mean "mixture"). According to the art, after stem cells are obtained from a tissue or organ source, they can be plated for 3 days before the nonadherent cells are removed from culture (Haynesworth et al., col. 4, lines 25-28). As such, an artisan practicing the claimed invention, using the teachings of Katz et al. and Akanbi et al. and removing the nonadherent cells 3 days after plating, as taught by Haynesworth et al. would have arrived at the cells claimed in claims 49 and 50. It is noted that it would have been routine in the art to practice the claimed invention for obtaining adherent cells 12 hours after plating and 3 days after plating as the art teaches that stem cells are the cells that adhere to the culture dish. As such, it would

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have been design choice for an artisan to remove debris and nonadherent cells 12 hours or 3 days after plating and thus, an artisan would have arrived at the claimed invention.

Claims 1-7, 9-12, 26-28, 48, 51, 52 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al., PCT Publication No. WO 00/53795, publication date, September 14, 2000, previously cited, in view of Akanbi et al., 1994, J. Anim. Sci., 72: 2828-2835, West, US Patent 5,589,483, patented December 31, 1996.

As discussed above, the combined teachings of Katz et al. and Akanbi et al. provide guidance for an artisan to obtain stem cells from adipose tissue of children.

While Katz et al. and Akanbi et al. provide this guidance, they do not teach that the stem cells exhibit “endogenous beta-galactosidase activity of less than 0.05% at 60 population doublings” (see claim 1).

The art at the time of filing teaches that recombinant vectors that comprise the HIV long terminal repeat (LTR) promoter positioned to drive expression of a reporter gene product can be used to indicate cell senescence (West, col. 8, line 60 to col. 9, line 12).

All the component parts are taught by Katz et al., Akanbi et al., and West. The only difference is the combination of the old elements into a single cell that expresses beta-galactosidase. It would have been obvious for an ordinary artisan to use an expression vector that comprises a reporter gene operably

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linked to an LTR promoter and to use it in stem cells. An artisan would have done so to determine whether a stem cell population in question was senescent.

Thus, the claims are rejected.

It is noted that claim 1 has been written to indicate that the claimed stem cells have “an endogenous beta-galactosidase activity of less than 0.05% at 60 population doublings”. In looking at the specification, page 24, Figure 1, Applicant's phrase appears to mean that less than 0.05% of the cells at confluence at the 60 population doubling stage express beta-galactosidase. As such, the claim has been interpreted in this way. In addition to this, it is noted “endogenous” expression of beta-galactosidase has been interpreted to mean expression of beta-galactosidase from a vector comprising a lacZ gene operably linked to a promoter. In this case, the promoter is the LTR promoter (e.g. specification, page 24, Figure 1, also pages 52-53, Example 9).

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Joanne Hama/
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